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Attorney Docket No. P29693

In re application of Peter HIMMELSBACH et al.

Confirmation No. **5165**

Application No. : 09/601,029

Group Art Unit : 1771

Filed : July 26, 2000

Examiner : Piziali, Andrew T.

For : SUPPORTING MATERIAL FOR MEDICINAL PURPOSES

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Commissioner for Patents
 U.S. Patent and Trademark Office
 Customer Service Window, Mail Stop AF
 Randolph Building
 401 Dulany Street
 Alexandria, VA 22314

Sir:

Transmitted herewith is a **Pre-Appeal Brief Request for Review** in the above-captioned application.

_____ Small Entity Status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a previously filed statement.

X A Notice of Appeal.

_____ A Request for Extension of Time.

The fee has been calculated as shown below:

Claims After Amendment	No. Claims Previously Paid For	Present Extra	Small Entity		Other Than A Small Entity	
			Rate	Fee	Rate	Fee
Total Claims: 62	*62	0	x25=	\$	x 50=	\$ 0.00
Indep. Claims: 2	**3	0	x100=	\$	x200=	\$ 0.00
Multiple Dependent Claims Presented			+180=	\$	+360=	\$ 0.00
Extension Fees for _____ Month(s)				\$		\$ 0.00
Notice of Appeal Filing Fee						\$500.00
Total:				\$	Total:	\$500.00

* If less than 20, write 20

** If less than 3, write 3

_____ Please charge my Deposit Account No. 19-0089 in the amount of \$_____.

X A check in the amount of \$500.00 to cover the filing fee is included.

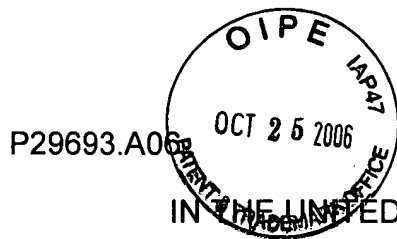
X The U.S. Patent and Trademark Office is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 19-0089.

X Any additional filing fees required under 37 C.F.R. 1.16.

X Any patent application processing fees under 37 C.F.R. 1.17, including any required extension of time fees in any concurrent or future reply requiring a petition for extension of time for its timely submission (37 C.F.R. 1.136(a)(3)).

Heribert F. Muensterer
 Reg. No. 50,417

Neil F. Greenblum
 Reg. No. 28,394



P29693.A068

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Peter HIMMELSBACH et al.

Confirmation No. 5165

Group Art Unit: 1771

Serial No. : 09/601,029

Examiner: Piziali, Andrew T

Filed : July 26, 2000

For : SUPPORTING MATERIAL FOR MEDICINAL PURPOSES

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Window, Mail Stop AF
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Applicants hereby request review of the final rejection of claims 37-98 dated August 2, 2006 in the above-identified application. No amendments are being filed with the request.

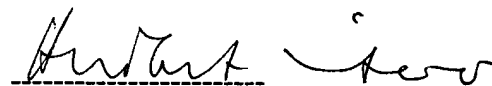
This request is being filed with a notice of appeal.

The review is requested for the reasons stated on the attached five sheets.

If there are any questions about this application, the Examiner is invited to contact the undersigned at the telephone number listed below.

P29693.A06

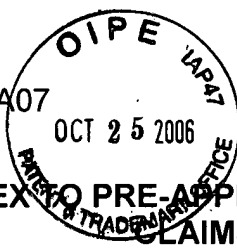
Respectfully submitted,
Peter HIMMELSBACH et al.

A handwritten signature in cursive script, appearing to read "Neil F. Greenblum", written over a horizontal dashed line.

Neil F. Greenblum
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October 20, 2006
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**ANNEX TO PRE-APPEAL BRIEF REQUEST FOR REVIEW OF REJECTION OF
CLAIMS 37-98 OF APPLICATION NO. 09/601,029**

The following is Appellants' statement pointing out clear errors in the Examiner's rejection and the Examiner's omissions of essential elements needed for a *prima facie* rejection:

Appellants note that all claim rejections under 35 U.S.C. § 103(a) set forth in the Final Office Action of August 2, 2006 are based on at least three documents, i.e., U.S. Patent No. 5,527,536 (hereafter "MERKLE"), U.S. Patent No. 6,479,073 (hereafter "LUCAST" and U.S. Patent No. 5,547,223 (hereafter "KOKETSU"). In this regard, the rejection alleges that MERKLE "discloses that the backing layer may be a polyester film (see Examples) but MERKLE is silent with regards to specific polyester film structures" wherefore "it would have been necessary and thus obvious to look to the prior art for conventional backing layer structures".

The rejection further alleges that LUCAST "provides this conventional teaching showing that it is known in the art to use a nonwoven backing layer overstitched with yarns". The rejection concedes that LUCAST fails to mention how many stitches (per cm) are present on the backing layer, but asserts that KOKETSU discloses that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, wherefore it would allegedly have been obvious to one of ordinary skill in the art "to provide 5 to 50 longitudinal stitches per cm in order to create a stitch-bonded fabric with a desired strength and rigidity".

This rejection is without merit for various reasons. For example, it is not correct that MERKLE "is silent with regards to specific polyester film structures". On the

contrary, it appears that each of the Examples of MERKLE specifies not only the thickness of the polyester film which is used as backing layer, but additionally specifies the thickness of the (second) polyester film which is silicone-coated and serves as a removable protective layer. In this regard, col. 6, lines 1-10 of MERKLE may, for example be referred to.

For this reason alone and additionally in view of the fact that in all of the numerous Examples of MERKLE a polyester film is employed as backing layer, one of ordinary skill in the art would not have been motivated at all to look for materials which can replace the polyester film of MERKLE. However, even if one were to assume, *arguendo*, that one of ordinary skill in the art would have been motivated “to look to the prior art for conventional backing layer structures”, this would not amount to a motivation to replace the polyester film of MERKLE with any other conventional backing material structure.

Further, even if one were to assume, *arguendo*, that one of ordinary skill in the art would have been motivated to replace the polyester film of MERKLE with any other conventional backing material structure, it is not seen what would have motivated one of ordinary skill in the art to select an overstitched nonwoven from the many types of backing materials disclosed by LUCAST, i.e., a material that is neither recommended by LUCAST nor used in any of the Examples of LUCAST. In fact, it appears that the backing materials employed in the 81 exemplary articles of LUCAST are exclusively polyester films, polyurethane films or polyurethane blown microfiber backings.

Moreover, the fact that polyester films are employed in many of the exemplary articles of LUCAST would even seem to reinforce the impression conveyed by

MERKLE, i.e., that polyester films are a very good choice for the backing material of the laminate of MERKLE. In other words, this fact would appear to be a disincentive rather than a motivation to replace the polyester film of MERKLE by any other (conventional) backing material and in particular, a material that is neither specifically pointed out nor particularly recommended by LUCAST. In other words, even if one were to assume that one of ordinary skill in the art could replace the polyester film of MERKLE by an overstitched nonwoven, the question still remains why he or she would do so.

Appellants note that in the Advisory Action mailed October 12, 2006 the Examiner argues that LUCAST “discloses that it is known in the art that a nonwoven, overstitched by yarns, is a viable backing layer alternative to a polymeric film”. Even if the Examiner were right in this regard, the mere fact that a nonwoven which is overstitched by yarns is a viable backing layer (as are many other materials, as also illustrated by LUCAST) does not provide any motivation to replace the polyester film of MERKLE with this nonwoven (or any of the other viable backing materials mentioned in LUCAST) unless one would recognize or at least have a reasonable expectation that the nonwoven provides significant advantages compared to a polyester film (these advantages not being (over)compensated by any disadvantages). The Examiner does not allege corresponding advantages, let alone explain what they would be.

At any rate, one of ordinary skill in the art even would recognize or at least expect significant disadvantages associated with the use of an overstitched nonwoven (or any porous material) instead of a (polyester) film, which constitutes at least one reason why one of ordinary skill in the art would be discouraged from using any nonwoven as replacement for the polyester film backing material of MERKLE:

According to MERKLE, the active substance that is to be incorporated into the pressure-sensitive adhesive is a substance which, at the temperature at which the adhesive bonds, is a readily volatile liquid (see, e.g., Abstract of MERKLE). It would be immediately apparent to one of ordinary skill in the art that in the case of using a (porous) nonwoven instead of a (polyester) film as backing material for the self-adhesive matrix of MERKLE there would be a substantially higher risk for the active substance to evaporate through and/or ooze out of the backing material during use and/or storage of the laminate than in the case of a (polyester) film.

In this regard, the Examiner argues in the Advisory Action that “the applicant has failed to show, or attempt to show, that the adhesive would necessarily flow through the nonwoven material”. Appellants note that in the present context it is of no importance whatsoever whether or not the adhesive of MERKLE would actually and necessarily flow through the nonwoven as long as it is reasonable to assume that there is a non-negligible risk that this will happen (or at least a significantly higher risk than in the case of a (polyester) film). Appellants maintain the position that is reasonable for one of ordinary skill in the art to assume that there is a substantial risk for the active substance of MERKLE to evaporate through and/or ooze out of a (porous) nonwoven, especially if a corresponding laminate is stored over prolonged periods of time.

Even if one were to assume, *arguendo*, that despite all of the facts set forth above one of ordinary skill in the art would still be motivated to replace the polyester film of MERKLE by an overstitched nonwoven, it is not seen why he or she would additionally be motivated to use a nonwoven that is overstitched by yarns with a number of stitches of at least 3/cm of web as it is recited in the present independent claims.

Applicants note that in this regard the rejection relies on column 7, lines 16-32 of KOKETSU which allegedly discloses “that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, with more stitches supplying a stronger web”.

This argument is without merit as well. Specifically, KOKETSU constitutes non-analogous art in that it does not relate to any article for use in medicine, let alone to an article for application to the skin, but to a webbing for restraining a vehicle occupant such as a safety belt (see, e.g., front page of KOKETSU).

Also, KOKETSU relates to a webbing, i.e., the opposite of a nonwoven material.

Even further, the passage of KOKETSU which is relied on in the rejection, i.e., column 7, lines 16-32, does not even appear to mention the number of stitches per unit of length, let alone in the context of strengthening the webbing. All that is mentioned in this passage is the number and length of stitch rows, i.e., not the number and/or length of stitches.

To sum up, for at least all of the reasons set forth above, the Examiner has failed to establish a *prima facie* case of obviousness with respect to any of the rejected claims.